NEGOTIATED RULEMAKING COMMITTEE ON THE SHARED RISK EXCEPTION

MINUTES[1]

December Meeting
December 16-18, 1997

The Negotiated Rulemaking Committee on the Shared Risk Exception held its sixth meeting on December 16-18, 1997 in Washington, D.C. The list of Committee Members and/or their alternates who attended is at **Attachment A**.

The facilitators reviewed the proposed agenda, noting that the goal for the meeting was consensus since there was no guarantee of a further meeting, merely the possibility of a January meeting if the Committee were close to consensus.

The Federal agencies then circulated a revised proposal (draft version dated 12/15/97 at 5:00 p.m.) for concepts to be developed into an interim final rule establishing standards for the statutory shared risk exception and a proposed rule (or possibly an interim final rule) for related regulatory safe harbors. The Federal agencies described how the proposal discussed at the November meeting had been modified in response to Committee Members' proposals submitted at or since that meeting. On December 16 and the morning of December 17, the Committee discussed the provisions of the revised draft (and related preamble topics). Committee Members identified remaining concerns, as well as some new concerns raised by the modifications or by Members who had not been present at the last meeting. The Committee then adjourned until 10:30 a.m. on December 18, to permit Committee Members to submit specific proposals for further modifications and to permit the Federal agencies to make some changes in response to the discussion and further proposed modifications.

On December 18, the Federal agencies presented a new draft proposal (version dated 12/18/97 at 9:30 a.m.), noting that they had not been able to obtain complete clearance of the new draft. They also distributed a new list of preamble topics. After caucusing, Committee Members each gave a general reaction to the new draft, indicating the primary issues, if any, which would need to be addressed satisfactorily before their constituents could "live with" the result. These primary issues were then discussed and a few additional issues identified. A draft of potential agreement terms was offered by the facilitators, and

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[1] These minutes were prepared by the facilitators for the convenience of the Committee Members and should not be construed to represent the official position of the Committee or of any Member on what transpired at the meeting.

Committee Members suggested some changes.

The Committee decided to meet in January, but for two days rather than three. The Committee then discussed what steps could be taken before the January meeting to move the Committee to consensus and what should take place at the January meeting.

These minutes first set out the major areas of discussion on various parts of the proposal, major changes made or to be considered in the proposed concepts for the rule or its preamble, and the primary remaining issues. The minutes then describe generally the discussion about potential agreement terms. Finally, the minutes set out the schedule for next steps in the Committee's negotiations.

Managed Care Organizations under Federal Health Care Programs

The first part ("prong 1") of the proposal would protect from anti-kickback liability remuneration between a "covered entity" and a "first tier provider", as well as certain "downstream" arrangements between providers, subject to certain standards. The Committee discussed the need to clarify what "provider" in this context means. (One suggested definition was "an individual or entity arranging for or providing items or services, or a combination thereof.")

The Federal agencies emphasized again that their proposal to provide broad protection for covered entities contracting with Federal health care programs and related downstream arrangements (with no requirement for "substantial financial risk") is contingent on other Committee Members concurring in narrow definitions of "organization" and "substantial financial risk" in the second part of the proposal.

COVERED ENTITIES

Major concerns, discussion points, changes, and remaining issues about "COVERED ENTITIES" were as follows:

- Although some revisions were made to the November proposal to describe what Medicaid managed care organizations would be covered, some additional revisions were suggested to reflect recent amendments to section 1903(m) of the Social Security Act and to protect some additional section 1115 waiver programs that Members thought should be protected (including Arizona's program). Members generally thought that these changes could be worked out by the next meeting.

- Members representing health plans questioned excluding

Federally qualified HMOs (FQHMOs) without Medicare risk contracts, in light of the reference in the shared risk exception under section 216 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to "eligible organizations under section 1876" of the Social Security Act. A revision was made in the 12/18/97 draft in response to this concern, but questions remained about protections for FQHMOs' commercial contracts with respect to enrollees where Medicare is primary payor on a fee-for-service (FFS) basis. One suggestion was to protect arrangements between FQHMOs and "first tier" providers related to their commercial business, but not to protect (under the first prong) downstream arrangements where Medicare is primary.

- For similar reasons, Members questioned excluding HMOs or competitive medical plans with Medicare contracts where reimbursement is on a cost basis. They indicated that this is still a concern until the year 2002. A revision was made in the 12/17/97 draft in response to this concern. A question remains about whether protection for cost-based Medicare contracts should extend only to first tier relationships.

- The Federal agency representatives indicated that they had not been able to complete consultations with the Department of Defense (DOD) about whether contractors with DOD's Tricare program should be covered entities. One health plan representative indicated that covering Tricare is important to her constituents and could affect her ability to reach consensus.

- Concerns were raised about how to cover additional Federal demonstration projects, including ones that might be created in the future. The suggestion was made that there be a "catch-all" provision. The Federal agencies indicated that they could not adopt this suggestion unless they had a specific proposal with language narrow enough to exclude projects that they see as offering insufficient protection against overutilization (for example, social HMOs). They further indicated, however, that the preamble could mention that advisory opinions could be requested on demonstration projects not covered by the rule. The list of preamble topics was revised accordingly.

In addition, a question was raised about whether HCPPs should be covered or whether they were reimbursed on an FFS basis that would make coverage under the first prong inappropriate.

"FIRST TIER" PROVIDERS

Some editorial changes were made in the 12/18/97 draft provision on "first tier" providers in response to suggestions.

Additional discussion points included the following:

- It was clarified that, for a joint venture (for example, an ambulatory service center owned by surgeons), remuneration between a covered entity and the joint venture ASC could be protected, as could FFS payments to the surgeons from the ASC for surgical services provided by the surgeons, but profit distributions to the surgeons would not be protected under this safe harbor (although such distributions might be protected under another safe harbor). A preamble topic was added to clarify this point.

- Section (D) of the provision would exclude Federally qualified health centers (FQHCs) from protection under the first prong. A representative of health centers indicated that this may prevent them from coming to consensus. Further discussions will be held with the Federal agencies to resolve this problem.

"DOWNSTREAM" PROVIDERS

The concerns with respect to the provision on "first tier" providers were also raised in connection with "downstream" providers.

With respect to the terms "upstream" and "downstream" used by the Committee, it was clarified that a provider making a payment to another provider would be "upstream," and the provider receiving the payment would be "downstream."

NO SWAPPING - UNPROTECTED SWAPPING

The proposed provision previously referred to as the "no swapping" provision was renamed the "unprotected swapping" provision, in response to a comment that the provision merely describes activities that would remove a transaction from safe harbor protection.

While Members indicated that the provision had been improved, they raised the following concerns about the provision, some of which resulted in modifications:

- A physician representative expressed concern that, if information about the provision is not disseminated

carefully, "risk-averse" counsel will interpret it too broadly and it will drive the marketplace in a way detrimental to patients, as well as physicians. He later suggested that the preamble make clear that many arrangements may still be legal, even if not protected under the rule, and provide guidance on how to analyze such arrangements. The Federal agencies noted that their proposal on preamble topics includes discussing that lack of protection does not automatically mean an illegal kickback. They rejected the idea, however, of providing general guidance in the preamble. In addition to expressing concern that they could not address every possible factual scenario, they noted that listing analytical factors--and other related laws that potentially could be violated--might not have the effect desired.

- Clarification was sought on how the parenthetical "(other than that covered by the written agreement)" in the first sentence of the 12/15/97 draft provision would affect analysis of a contract with single or multiple lines of business. The Federal agencies clarified that they meant "covered by the arrangement" and made a change in the 12/18/97 draft to correct this.

- A few Committee Members questioned whether the first sentence in the provision was needed, particularly if the Federal health care programs are paying on a capitated basis. A policy question was raised concerning agreements where both Medicare and Medicaid are paying on a capitated basis, but Medicaid is paying less. A change was made in the 12/18/97 draft to add at the end of the first sentence (after "payment is made in whole or in part by a Federal health care program") the phrase "on a fee-for-service or cost basis."

- Concern about the phrase "shifts the burden" in the second sentence of the provision was addressed by adding a preamble topic to clarify that it means shift the financial burden. A proposed language change to the sentence itself was rejected on the ground that the phrase is used in other safe harbor regulations and changing it might cause confusion.

In response to the addition of "cost basis" to the first sentence of the provision, a few Committee Members representing health plans indicated that they would need to consult further with their constituents to see if this would cause problems.

DEFINITIONS

The Committee discussed whether the definition of "items or services" included services provided to providers (such as disease management). A preamble topic was added to clarify that such services could be covered under the "reasonably related" part of the definition.

The Committee also discussed what constitutes marketing and whether marketing services would be excluded from the definition only if provided to potential enrollees prior to their enrollment in the plan. The 12/18/97 draft includes a revision to indicate that all marketing services would be excluded, whenever provided, as well as other services provided prior to enrollment. The Federal agencies explained that marketing was not covered because of past abuses with marketing. The representative of independent insurance agents indicated that they were willing to work with the Federal agencies to develop a separate safe harbor addressing the marketing issues, rather than blocking consensus.

Preamble topics were added to clarify that simply because marketing is not covered does not mean it is *per se* illegal and that nurse call-in lines for current enrollees of an organization are not marketing under this provision.

Managed Care Risk-Sharing Arrangements Where Federal Program Pays Fee-For-Service

The second part ("prong 2") of the proposal addresses remuneration pursuant to risk sharing arrangements between an organization and a "first tier" provider, or between two providers downstream, where the providers are at substantial financial risk. The Committee discussed the scope of prong 2 as applying primarily to arrangements where Medicare is primary payor on an FFS basis for retirees in an employer plan. The proposal notes that it would also apply to section 1115 Medicaid waivers that do not fit under prong 1.

The Federal agencies explained that the intent of their proposal was to limit protection under prong 2 to situations where the Federal health care program enrollees would be treated the same from the perspective of the providers as other enrollees, in spite of the FFS payment.

ORGANIZATION

Committee Members representing providers expressed continuing concerns with the narrowness of the definition of "organization," particularly with respect to exclusion of self-funded ERISA plans and third party administrators (TPAs) and the requirement for State licensure. One Committee Member indicated, however, that consensus of State regulators with the proposal would be

jeopardized if this were changed. The Federal agencies explained their concern that employers and TPAs would have no incentive to reduce FFS claims to Federal health care programs.

One Committee Member suggested that the preamble indicate that there was no consensus on the definition of "organization" since providers would like a broader definition. This idea was rejected as inconsistent with the Committee's Organizational Groundrules on consensus. It was noted that consensus means only that the party can "live with" the result. A preamble topic was added to indicate that consensus will be explained. In addition, it was noted that the definition of organization might be subject to further amendment, and a preamble topic was added to indicate that the IG would consider amending the regulation at a later point through the annual solicitation for new safe harbors. The promulgated regulation would, however, define the scope of "organization" under section 216, the IG representative indicated.

Concerns were raised about the effect of the 50% requirement in section (I) of the 12/15/97 draft (later changed to (G)) on services provided mostly to Medicare beneficiaries, such as long-term care. The preamble would clarify that the 50% requirement applies to the agreement between the organization and the first tier provider only and does not extend downstream. One Committee Member continued to question the need for the 50% requirement at the first tier level.

In addition, the following changes were made or suggested in the proposed provision defining "organization":

- The phrase "which functions as part of a managed care system" in the first sentence of the provision in the 12/15/97 draft was deleted as unnecessary and potentially confusing.

- The second sentence of the provision was changed in the 12/17/97 draft to describe the written agreement as providing for the listed requirements, rather than the organization.

- The term "actuarially sound" was deleted in section (A) and replaced with the modifier "reasonable." A health plan representative who is an actuary had indicated that an arrangement would be actuarially sound if it would be solvent at the end of the year. The Committee discussed the goal of avoiding manipulation of utilization targets and how to accomplish this goal.

- Changes were made in the 12/18/97 draft to consolidate requirements related to quality assurance and to eliminate wording about providing "measurable goals for improving coordination of care" that was considered problematic. The revision included the phrase "measurable patient outcomes" and this led to a discussion of whether outcomes are measurable for every type of service. Further changes will be considered (although a consumer representative expressed concern that changes not weaken the provision since consumers consider financial incentives for quality care to be important). In addition, in response to consumer concerns that the providers have quality incentives, quality assurance provisions were added to the definition of "written agreement" under DEFINITIONS.

- Changes were made to the provision in the 12/15/97 draft at section (G) to clarify that the payments which must be on a periodic basis are the premiums under the risk sharing arrangement. (See section F of the 12/18/97 draft.) A suggestion that the wording be changed to "primarily on a periodic basis" was rejected as potentially undercutting the requirement and permitting lump sum reconciliation. A continuing concern was mentioned regarding how the requirement for payments on a periodic basis would be affected by payments commonly made outside a premium structure, such as stop-loss or coverage of expensive procedures such as heart transplants. A preamble topic was added to clarify that FFS or case rate payments for specific items or services such as transplants would not disqualify an arrangement that otherwise shares risk from being a risk sharing arrangement, but payments outside the arrangement would not be protected and would be scrutinized for swapping. Further discussion of this may be needed.

- The requirement in the 12/15/97 draft (section I) that there be "at least 50% non-Medicare beneficiaries as enrollees" was changed to "at least 50% non-Federal health care program beneficiaries as enrollees where a Federal health care program is not primary." (See section G in the 12/18/97 draft.)

- Changes were made to clarify the requirement for treating Federal health care program beneficiaries no differently than other enrollees to indicate that it is their status as beneficiaries that cannot lead to different treatment. These changes were made in response to concerns that reimbursement rates usually vary according to patient characteristics and that this should not be viewed as different treatment that would disqualify an arrangement

from protection.

"RISK SHARING ARRANGEMENT"

In response to Committee Member concerns, the following changes were made to the provision on "risk sharing arrangement":

- References to Medicare were changed to refer to Federal health care program.
- Provisions intended to require that payor sources or billing methods not affect rates were clarified to indicate that payment adjustments related to utilization patterns and costs of the relevant population would not be disallowed.
- Changes were made to clarify that arrangements would be qualifying for protection, rather than organizations.
- The provision was clarified to indicate that arrangements where the provider bills the Federal health care program directly on a cost basis would not be protected.

The addition of a provision to the 12/15/97 draft regarding provider ownership generated significant concerns for provider representatives. The Federal agencies indicated that they were open to suggestions for how to make this provision more specific, but explained their concern that ownership might permit a structure where distributions to owners dilute the actual risk, particularly for an entity owned by only a few providers. Some Members indicated that they would come up with specific proposals to limit this provision since otherwise it would be another barrier to provider ownership, which in their view is beneficial.

"SUBSTANTIAL FINANCIAL RISK" (SFR)

With respect to the **payment methodology standard** for SFR, there was considerable discussion of whether prospective per diem rates should be included. The Federal agencies reiterated their concern that there are insufficient controls over the number of days of service provided when payment is on an FFS basis, indicating that they had not yet seen a satisfactory proposal to address this concern. Provider representatives indicated that, in addition to utilization review requirements, there may be other disincentives to overutilization (such as copay requirements) where payment is on a prospective per diem basis. They indicated they would propose specific language to identify such situations.

In addition, some Committee Members indicated that there may be case rates (including some new TEFRA rates), bundled rates, or

global fees that include inpatient stays, so that there would be the same control over the number of admissions as with an inpatient DRG--that is, the fact that it is undesirable for a patient to be hospitalized would make overutilization less of a concern. The Federal agencies indicated that they would give such payment methodologies further consideration, but that in no event would they cover psychiatric services. Hospital representatives questioned this condition. The Federal agencies explained that, given their experience, they would not have the same level of comfort for psychiatric admissions that the number of admissions would not be manipulated.

In addition, the 12/18/97 draft provision on payment methodology standard added back in the modifier "full" before the word "capitation." (The modifier "full" had been deleted from the 12/15/97 draft based on comments at the November meeting.) Committee Members expressed concern with this modifier. The Federal agencies explained that discussion about arrangements that are not pure capitation but involve various other payments (such as withholds) led them to be concerned about protecting all arrangements involving capitation.

With respect to the **numeric standard**, the provision had been changed from the November proposal of 20% for all providers to a proposal for 16% for non-institutional providers and 8% for institutional providers. The Federal agencies explained that the rationale for distinguishing institutional and non-institutional providers was that institutional providers have greater capital costs affecting what risk they can bear. The Federal agencies indicated that they still had not received any data to support varying percentages for different provider types. They agreed to request such data in the preamble. Representatives of pharmacies and pharmaceutical manufacturers indicated that they would propose a lesser percentage for their constituents since they cannot bear risk comparable to other non-institutional providers like physicians.

The Federal agencies were asked to reconsider defining "target payment" as dependent on "meeting" utilization targets, as opposed to "exceeding" the targets, in light of the fact that there is a range of expected utilization that would be reasonable. There was some discussion of whether the provision could be amended to include payments meeting or exceeding a target, but with some sort of limit so that only reasonably expected bonuses would be included. The Federal agencies indicated that, if such a change were made, they might have to reconsider whether to reduce the percentage standard from the 20% they originally proposed.

In response to Committee concerns about clarity, changes were made in the 12/18/97 draft to substitute other language for the

reference in the numeric standard to "actuarially sound" utilization targets and to substitute the word "guaranteed" for the word "minimum" in the definition of "minimum payment." In addition, a preamble topic was added to clarify that, in year one of an arrangement, it would not be necessary to include in the SFR calculation performance bonuses achieved by 75% of the participating providers. Additional clarification of what is meant by "participating provider" may be needed.

The reference to the physician incentive plan (PIP) rule threshold for substantial financial risk (added to the proposal after the November meeting) was modified in the 12/18/97 draft to clarify that arrangements with risk greater than 25% risk as calculated in the PIP rule would qualify. One Committee Member suggested that the PIP exclusion of arrangements involving a patient panel size of 25,000 lives or greater was inappropriate for the safe harbor rule. Another suggested that the safe harbor should protect arrangements where the risk as calculated under PIP is 25% exactly. The Federal agencies indicated that they were willing to accept the PIP rule calculations as constituting SFR (even though that calculation includes some theoretical bonuses), but were not willing to accept it with the suggested modifications.

"OBLIGATED TO PROVIDE"

In response to Committee Member comments, some editorial changes were made in the 12/18/97 draft provision on "obligated to provide."

DOWNSTREAM PROVIDERS

One Committee Member suggested protection for the arrangement between levels 3 and 4 described in the provision on downstream providers. The Federal agencies rejected this suggestion on the basis that the provider at level 3 would get paid more if more services were provided and therefore would have no incentive to control utilization.

DEFINITIONS

Concerns regarding definitions of "items or services" and "written agreement" had previously been raised in connection with other provisions and were addressed by changes in the 12/18/97 draft.

NO SWAPPING - UNPROTECTED SWAPPING

Most concerns regarding the "no swapping" provision in prong 2

had previously been raised in connection with the related provision for prong 1. With respect to the second bullet in the provision in prong 2, one Committee Member raised some concerns about wording and changes were made in the 12/18/97 draft.

Draft agreement terms

The facilitators circulated a new draft of agreement terms based on the Committee's Organizational Groundrules. Articles 4, 5, and 11 of the new draft reflect the fact that part of the proposal being considered depends on the Secretary of Health and Human Services exercising her discretionary authority to promulgate regulatory safe harbors and that Committee Members' agreement not to file negative comments would be contingent on exercise of that authority consistent with the Committee consensus. The IG representative indicated that the IG would propose language to make this more explicit. He also indicated that the Federal agencies were considering making the entire rule an interim final rule, rather than having the part under the Secretary's regulatory authority be a proposed rule.

Committee Members indicated that they wanted to clarify that they could provide comments on a specific part of the rule if the preamble specifically solicits comment on that part.

Committee Members also indicated that, if a Committee Member determines that it has a right to submit negative comments because what is published does not have the same substance and effect as the Committee Statement, the Committee Member should be required to notify other Committee Members and to state the basis for this determination.

Committee schedule

The Committee discussed the next steps in the negotiations and set the following schedule:

- Any additional proposed modifications must be submitted by COB on **December 29** to Mac Thornton (FAX: 202- 205-0604) and Judy Ballard (FAX: 202-690-5863).

- The Federal agencies will respond with a new draft by **January 8**, and the new draft will be FAXed to Committee Members the next day.

- Committee Members will review the new draft as soon as possible to identify any concerns that could prevent them from coming to consensus ("drop dead" issues) and will attempt to work out a resolution with other Committee Members before January 21.

- The Committee will meet on **January 21** for input on the new draft, beginning at 9:00 a.m. The meeting will adjourn for the day at 3:00 p.m. to permit Committee Members to consult with their constituents about any additional changes.

- The Committee will reconvene on **January 22** to sign an agreement if consensus has been achieved.

The January meeting will be held at the Holiday Inn Capitol, 550 C Street, S.W., Washington, D.C.

ATTACHMENT A - LIST OF PARTICIPANTS

Committee Members present for part or all of the meeting:

Candace Schaller, AAHP
Cheryl Matheis, AARP
Mary R. Grealy, AHA
Edward B. Hirshfeld, AMA
Brent Miller, AMGA
Susan E. Nestor, BCBSA
Charles P. Sabatino, CCQHC
Missy Shaffer, CCC
Laura Thevenot, FAHS
Eddie Allen, HIMA
Stephen M. Spahr, NAMFCU
S. Lawrence Kocot, NACDS
Karen A. Morrissette, DOJ
D. McCarty Thornton, OIG/HHS
J. Mark Waxman, TIPAAA

Alternates substituting for Committee Members:

Thomas Wildsmith, HIAA
Marjorie Powell, PhRMA
Jennifer Goodman, NASMD
Mary Beth Senkewicz, NAIC
Roger, Schwartz, NACHC
Howard Sollins, AHCA
Janet Stokes, IIAA/NAHU/NALU

Alternates attending and/or substituting for Committee Member for part of the meeting:

Mark Joffe, AAHP; Kathy Nino, AMA; Mary L. Kuffner, AMGA; Bob Wallace, DOJ; Douglas Guerdat, BCBSA; Mark H. Gallant, NACDS; Kevin McAnaney, OIG/HHS; Marcie Zakheim, NACHC; Barbara Zelner, NAMFCU.